

## Subpart F—Submission of Bids and Monthly Beneficiary Premiums; Plan Approval

### § 423.251 Scope.

This section sets forth the requirements and limitations on submission, review, negotiation and approval of competitive bids for prescription drug plans and MA-PD plans; the calculation of the national average bid amount; and the determination of enrollee premiums.

### § 423.258 Definitions.

For the purposes of this subpart, the following definitions apply:

*Full risk plan* means a prescription drug plan that is not a limited risk plan or a fallback prescription drug plan.

*Limited risk plan* means a prescription drug plan that provides basic prescription drug coverage and for which the PDP sponsor includes a modification of risk level described in § 423.265(d) in its bid submitted for the plan. This term does not include a fallback prescription drug plan.

*Standardized bid amount* means, for a prescription drug plan that provides basic prescription drug coverage, the PDP approved bid; for a prescription drug plan that provides supplemental prescription drug coverage, the portion of the PDP approved bid that is attributable to basic prescription drug coverage; for a MA-PD plan, the portion of the accepted bid amount that is attributable to basic prescription drug coverage.

### § 423.265 Submission of bids and related information.

(a) *Eligibility for bidding.* An applicant may submit a bid to become a Part D plan sponsor.

(b) *Bid submission*—(1) *General.* Not later than the first Monday in June, each potential Part D sponsor must submit bids and supplemental information described in this section for each Part D plan it intends to offer in the subsequent calendar year.

(2) *Substantial differences between bids.* Potential Part D sponsors' bid submissions must reflect differences in benefit packages or plan costs that CMS determines to represent substantial dif-

ferences relative to a sponsor's other bid submissions. In order to be considered "substantially different," each bid must be significantly different from the sponsor's other bids with respect to beneficiary out-of-pocket costs or formulary structures.

(3) CMS may decline to accept any or every bid submitted by a Part D sponsor or potential Part D sponsor.

(c) *Basic rule for bid.* Each potential Part D sponsor must submit a bid and supplemental information in a format to be specified by CMS for each Part D plan it offers. Each bid must reflect a uniform benefit package, including premium (except as provided for the late enrollment penalty described in § 423.286(d)(3)) and all applicable cost sharing, for all individuals enrolled in the plan. Each bid must reflect the applicant's estimate of its average monthly revenue requirements to provide qualified prescription drug coverage (including any supplemental coverage) for a Part D eligible individual with a national average risk profile for the factors described in § 423.329(b)(1).

(1) *Included costs.* The bid includes costs (including administrative costs and return on investment/profit) for which the plan is responsible in providing basic and supplemental benefits.

(2) *Excluded costs.* The bid does not include costs associated with payments by the enrollee for deductible, co-payments, coinsurance, and liability above the plan allowance in the case of out-of-network claims, payments projected to be made by CMS for reinsurance, or any other costs for which the sponsor is not responsible.

(3) *Actuarial valuation.* The bid must be prepared in accordance with CMS actuarial guidelines based on generally accepted actuarial principles. A qualified actuary must certify the plan's actuarial valuation (which may be prepared by others under his or her direction or review), and must be a member of the American Academy of Actuaries to be deemed qualified. Applicants may use qualified outside actuaries to prepare their bids.

(d) *Specific requirements for bids.* The bid and supplemental information submission must include the following information: